Questions and Answers (Qs & As)

Proposed Drug Watch Program

Q 1: What is the Drug Watch Web page?

The Drug Watch Web page is a new communication channel FDA is proposing to communicate the most up-to-date information possible on emerging safety issues to the public, even before FDA fully determines the significance of that information or decides whether a regulatory action is appropriate. The Drug Watch Web page is not intended to identify specific drugs as being particularly risky. All drugs have risks, and patients and their healthcare professionals must balance the risks and benefits of a drug when making judgments about an individual patient's therapy.

Q 2: When will the Drug Watch Web page be online?

The Drug Watch Web page is not yet active. FDA is making a draft guidance available explaining the proposed Drug Watch program in more detail. FDA is soliciting input from the public on Drug Watch before implementing the program.

Q 3: What kind of information would the Drug Watch Web page contain?

Drug Watch, as proposed, would make ***emerging*** safety information available to the public. The Drug Watch Web page would contain factual information about new potential side effects and/or risks that could be avoided by selecting patients appropriately, monitoring patients adequately, avoiding drug-drug interactions, or preventing medication errors. There would also be links to helpful patient information sheets and healthcare professional sheets containing emerging safety information and information in formats designed specifically for healthcare professionals and consumers.

Under the FDA's proposal, the Agency would conduct a preliminary review of the emerging information to determine which newly reported safety information warrants public dissemination while FDA continues to scientifically evaluate the significance of the new data. FDA would work as quickly as possible to resolve safety issues identified with drugs listed on the Drug Watch Web page.

FDA would also post information about the status of its analyses of emerging safety information.

Q 4: What is an emerging risk?

An *emerging risk*, or emerging safety concern, is a possible serious new side effect, potentially related to a drug on the market, that has been reported to FDA and that FDA is analyzing. A side effect is considered new when, for example, the effect was not seen (or the rate or severity of the effect was not seen) during clinical testing, but was identified after the drug went on the market. For example, sometimes, after a drug is approved, rare but serious side effects may emerge as the drug is more widely used. Sometimes drugs

are prescribed for new uses (off-label uses) with unanticipated results. If FDA receives information that a drug interacts with another drug, and this interaction may be causing a serious side effect, this information would be considered *emerging*. This is the kind of information that would be posted on the Drug Watch Web page.

Q 5: Would the Drug Watch Web page cover all medical products?

No, Drug Watch would disseminate emerging risk information only about human drugs regulated by the Center for Drug Evaluation and Research (CDER) (i.e., drugs and therapeutic biological products, both prescription and over-the-counter products). Blood products and medical devices, for example, which are regulated by other FDA centers, will not be covered.

Q 6: Should the public stop taking a drug if information about the drug appears on the Drug Watch Web page?

The goal of the Drug Watch Web Page is to make emerging safety information available to healthcare professionals and patients so they can consider the information themselves and make better-informed treatment decisions. Posting information on the Drug Watch Web page would not mean that FDA has concluded there is a definitive causal relationship between a drug product and the risks or adverse events described, nor would it mean that FDA is advising practitioners to discontinue prescribing a drug. Furthermore, FDA would not expect companies to stop marketing a product just because information about that product appears on the Drug Watch Web page.

The Drug Watch Web page would provide a public forum in which FDA could communicate emerging safety information and trends while FDA continued to evaluate that information. All drugs have risks, and patients and their healthcare professionals balance those risks against a drug's benefits when making judgments about an individual patient's therapy.

Q. 7: What does it mean when FDA says a drug is safe?

FDA makes decisions about the safety of a particular drug after considering its benefits to treat a particular condition in relation to its risks. FDA therefore considers a drug safe when its benefits outweigh its risks for its intended use.

Drug Safety Oversight Board

Q 1: Who will serve on the Drug Safety Oversight Board (Board)?

The Deputy Director, Center for Drug Evaluation and Research (CDER) will serve as the Chair of the Board.

The voting members include the following representatives**:**

Center for Drug Evaluation and Research
- Office of Drug Safety – Three members and two alternates.
- Office of New Drugs – Three members and two alternates.
- Office of Counterterrorism and Pediatric Drug Development – One member and one alternate.
- Office of Compliance – One member and one alternate.
- Office of Pharmaceutical Science – One member and one alternate.
- Office of Clinical Pharmacology and Biopharmaceutics – One member and one alternate.
- Office of Biostatistics – One member and one alternate.

Center for Biologic Evaluation and Research
- One member and one alternate.

Center for Devices and Radiological Health
- One member and one alternate.

Non-FDA DHHS Agency (for example, the National Institutes of Health)
- One member and one alternate.

Non-DHHS Health Care Providing Agency (for example, the Veterans Administration)
- One member and one alternate.

Center for Drug Evaluation and Research (non-voting)
- Office of Medical Policy – One member.

The Board may also engage the Chairs of FDA Advisory Committees and other external scientific experts, as well as consumer and patient representatives as consultants to present views regarding emerging drug safety issues**.**

Q 2: How will individuals be selected to serve on the Board?

CDER's Center Director will request nominations for members and alternates from the directors of each organization represented on the Board and will recommend members to the Commissioner of FDA. The Commissioner will then appoint members to the Board from those recommended by CDER's Center Director.

Q 3: How often will the Board meet?

The Board will meet on an "as needed" basis, with meetings anticipated monthly at first.

Q 4: How will issues be selected for consideration by the Board?

Any organizational unit in CDER may refer a drug safety issue to the Board for assessment by submitting a request to the Executive Director. Also, on a monthly basis, the Office of Drug Safety (ODS) and the Office of New Drugs (OND) will nominate items.

Q 5: What process will the Board follow to make its recommendations?

Decisions made by the Board will serve as recommendations to CDER's Center Director. FDA expects most recommendations will be reached through consensus. When consensus cannot be reached, a vote will be taken.

Decisions made by the Center Director, based on recommendations made by the Board, will be implemented through the appropriate program office. The Center Director retains final authority for Center decisions. All recommendations of the Board may be appealed to the Center Director by a dissenting Office Director before the Center Director makes a final decision.

Q 6: How and when will the Board get input from non-government stakeholders such as consumer and patient groups?

The Board can engage consumer and patient representatives as consultants to present views regarding emerging drug safety issues.

Q 7: What information about the Board's deliberations will be made available to the public?

The Board often will be considering in its deliberations confidential commercial information and options and recommendations that are sensitive and pre-decisional, and normally not disclosed. Therefore, the deliberations of the Board will not be routinely disclosed. Requests for records must be submitted under the Freedom of Information Act, and will be handled in accordance with applicable laws and regulations governing disclosure. However, we expect to make information publicly available concerning emerging safety information on CDER's Web page via the proposed Drug Watch Program and the issuance of Patient and Healthcare Professional Sheets. This information will reflect the input of the Board. In addition, once the Proposed Drug Watch Program has been implemented, MedWatch will send the information on the Drug Watch via an e-mail notification to the MedWatch E-List and to the 160 organizations that work with FDA as MedWatch partners to leverage and amplify the timely dissemination of safety data.

Q 8: How will FDA ensure that the Board's deliberations are independent and not influenced by those involved in the approval and post-marketing review of the drugs?

The make up of the Board and the vesting of decision-making authority in the Center Director ensure that the Board's deliberations will be independent of the review process. Representatives of the Office of New Drugs comprise only 3 of the Board's 15 voting members. Members of the Board will be recused from voting on an issue concerning a specific drug if they have been directly involved in the regulatory decision-making (e.g., signed a regulatory action) concerning that drug. The Board will make recommendations to the Center Director who will make the final decisions on drug safety issues. The Center Director is not normally involved in the approval of new drugs.